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GRANT NUMBER DAMD17-94-J-4233

TITLE: Pain Management Skills for Minority Breast Cancer Patients

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REPORT DATE: September 1998

TYPE OF REPORT: Annual

PREPARED FOR: Commanding General  
U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;  
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DTIC QUALITY INSPECTED 4

19990811 100

# REPORT DOCUMENTATION PAGE

*Form Approved  
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1. AGENCY USE ONLY <i>(Leave blank)</i>			2. REPORT DATE September 1998		3. REPORT TYPE AND DATES COVERED Annual (15 Aug 97 - 14 Aug 98)		
4. TITLE AND SUBTITLE Pain Management Skills for Minority Breast Cancer Patients			5. FUNDING NUMBERS DAMD17-94-J-4233				
6. AUTHOR(S) Charles S. Cleland, Ph.D.							
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Wisconsin Madison, Wisconsin 53706-1490			8. PERFORMING ORGANIZATION REPORT NUMBER				
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSORING / MONITORING AGENCY REPORT NUMBER				
11. SUPPLEMENTARY NOTES							
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited				12b. DISTRIBUTION CODE			
13. ABSTRACT <i>(Maximum 200 words)</i>  This project developed patient educational materials, both video and written, for lower-income African American and Hispanic women. The development of the materials was guided by the results of three studies designed to establish the specific educational needs of women of each ethnic heritage. The results of the first study indicated that the majority of the minority women were receiving analgesics of insufficient strength to manage their pain and that their physicians underestimated pain severity. The African American women were more likely than the Hispanic women to take their analgesics only when necessary. The second study found that the health care providers of these women demonstrated conservative pain management practices. They reported inadequate pain assessment and patient reluctance to report pain as the top barriers to optimal pain treatment. The structured patient interviews in the third study revealed that minority women feel a need for more information about cancer-related pain, analgesic medications, and side effect management. The educational materials will be tested in a randomized clinical trial at sites that serve primarily minority patients. In order to train site personnel in the study procedures, a pilot study was initiated as a run-in phase for the clinical trial.							
14. SUBJECT TERMS Breast Cancer					15. NUMBER OF PAGES 23		
					16. PRICE CODE		
17. SECURITY CLASSIFICATION OF REPORT Unclassified		18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified		19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified		20. LIMITATION OF ABSTRACT Unlimited	

FOREWORD

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## INTRODUCTION

Improving pain control for patients with metastatic breast cancer will significantly reduce the morbidity of this disease. It is estimated that 185,700 women are newly diagnosed with breast cancer in the US each year (Parker et al., 1996). Approximately 70% of these women are diagnosed in the early stages of the disease, due mainly to progress in screening and diagnosis. Despite improvements in cancer care for patients with early stage disease, a large number of patients will still develop metastatic disease, and mortality rates for these patients remain relatively constant. Minority women are more likely than white women to have advanced disease at diagnosis, and treatment outcomes are worse for minority women (Freeman & Wasie, 1989). Improving the quality of life of patients who will die of their disease, especially controlling their pain, should be as much a priority for these patients as improving the therapeutic approaches for their disease.

Women with metastatic breast cancer, especially those from minority populations, are not receiving optimum pain control. While it is estimated that pain could be well controlled in over 90% of patients with cancer (Foley, 1985), data from a recent national study indicate that 43% of women with metastatic breast cancer and pain are not adequately treated by the standards of the World Health Organization (Cleeland et al., 1994). Compared with other patients who have pain due to metastatic disease, women are more likely to be undertreated, and patients from sites treating primarily African American or Hispanic patients are three times as likely to receive inadequate analgesics. Minority patients recognize that they are undertreated; they more frequently report that they need more medication for pain, that they have less pain relief from pain treatment and shorter duration of pain relief from their medications (Cleeland et al., 1997). They also report more pain-related impairment of function.

Poor cancer pain control is a function of many factors, including those related to the inadequate pain management given by health care professionals and those related to barriers created by the health care system in general. Patient concerns, expectations, and behaviors also contribute to poor pain management (Cleeland, 1984; Ward et al., 1993). These patient-related factors include the belief that pain is inevitable, fears of addiction to analgesics, fears of building tolerance to analgesics, and fear of reporting pain to providers.

This project has developed patient educational materials, both video and written, for African American women and women of Hispanic descent. The project began with studies designed to establish the specific educational needs of women of each ethnic heritage. In consultation with medical experts of both African American and Hispanic descent, video scripts were written that covered the perceived barriers to good pain control in both groups. These scripts were reviewed by separate focus groups of women with breast cancer and pain from each group to determine the best presentation style for the educational material. Specific educational material developed for each group, African American and Hispanic, will be tested in a randomized clinical trial, entering women with breast cancer from each heritage group.

This project is based on the premise that patients who expect pain relief and are able to communicate their distress are liable to promote more responsive pain management from their health care providers. Identifying patient concerns and behaviors that limit effective pain management and providing gender and heritage-specific information and skills training to modify these concerns and behaviors may present the most effective way, at least in the short term, to reduce the percentages of patients whose functioning is impaired by pain. The skills training for minority patients is predicated on our assessment of the specific information and skills they need to manage their pain.

## BODY

The first task in our statement of work was to assess the needs of minority breast cancer outpatients for information and skills needed to manage pain. The second task was to develop multi-media education and training materials that are linguistically and culturally appropriate for low socioeconomic status (SES) Hispanic and African American populations. The final task is to test the effectiveness of these materials in a randomized clinical trial. To accomplish these tasks, we formed a network of three urban public hospitals that treat minority patients and established a multi-disciplinary team to meet project goals. Using the results of baseline studies that assessed the educational needs of our patient populations, we produced and edited the educational materials. We will evaluate the effectiveness of the educational tools in a randomized, controlled clinical trial for low SES African American and Hispanic outpatients with metastatic breast cancer and disease-related pain. If this program is effective, it can easily be introduced by other care centers where these patients are treated.

In September of 1996, the Pain Research Group of the University of Wisconsin Medical School - Madison, the group responsible for the scientific and technical aspects of this project, relocated to the University of Texas M.D. Anderson Cancer Center (UTMDACC) in Houston. Because of Department of Defense policy, the awarded home of the project remains at the University of Wisconsin. Dr. Kurt Hecox, Professor of Neurology at the University of Wisconsin, agreed to be the project PI. In the fall of 1997 Dr. Hecox and the University of Wisconsin Medical School submitted a request to the Department of the Army to name Dr. Hecox as the replacement PI and to subcontract the project work to UTMDACC, with Dr. Cleeland as the subcontract PI. This request was approved, and the subcontract funds became available in February 1998. We also were given an extension of the funding period that will allow us to complete the project. Dr. Hecox serves as the administrator of the project subcontracts and assists in the coordination of site activity.

Our three sites currently are Jackson Memorial Hospital (University of Miami), Los Angeles County Medical Center (University of Southern California) and LBJ General Hospital in Houston, Texas. In order to facilitate recruiting and accrual, minority patients of lower socioeconomic status in the breast clinic at UTMDACC also will be recruited for the clinical trial. Vicente Valero, MD, Chief of Medical Oncology at LBJ Hospital and Assistant Professor of Medicine at UTMDACC, will supervise recruiting at LBJ and UTMDACC. Because of the relationship between UTMDACC and LBJ Hospital, no subcontract is required to have LBJ participate as a project site.

To assess the needs of minority breast cancer patients, two descriptive studies (Study 001 and Study 002) examined the environment in which these patients are treated and the type of treatment typically provided. These studies were completed at the Miami, Los Angeles, and Fort Worth sites. During the project period August 1997 to August 1998, these two studies were completed at the LBJ Hospital site. A summary of the overall findings from the two studies is included in this progress report. These results provide an estimate of the quality of treatment at each of the sites prior to the introduction of the educational intervention. The development of the intervention has also been guided by a third study: Structured interviews (Study 004) have been conducted with low SES African American and Hispanic women in Miami, Los Angeles and Fort Worth. A summary of the content analysis of the interviews is presented in the report.

During the period August 1997 to August 1998, the production of the two videotapes was completed. The scripts for the videos were finalized after analysis of focus group data and consultation with project consultants. A copy of the video for African American women, "Work with Me: Managing Cancer Pain" is included as Appendix I. The video for Hispanic women, "Haga

Algo! Maneje su Dolor" was completed in July 1998. The printed materials, booklets on pain management for African American and Hispanic women, were developed after consultation with experts on minority health education and pain management.

Prior to the completion of the educational materials, we initiated a pilot study to provide a run-in phase of the clinical trial. The purpose of the pilot study is to train the site research nurses and data managers in patient identification, recruitment, data management and data transfer procedures that the trial will employ. Each site is piloting the study with five to fifteen minority cancer patients. The video and handbook are those currently used in an Eastern Cooperative Oncology Group clinical trial (ECOG 3Z93) that also examines patient education for pain control. These materials, designed for majority patients, are not expected to be as effective as the tailored materials produced by this project.

Data management for the project is coordinated by Dr. Rodger Winn, director of the Community Oncology Program at UTMDACC, the data management center for the MD Anderson NCI-funded CCOP (Community Clinical Oncology Program) research base. A data base and a system for quality control of project data for the pilot study and clinical trial have been developed.

## **SUMMARY OF RESEARCH FINDINGS TO DATE:**

### **Study 001 - Outpatient Pain Needs Assessment Survey (Task 1)**

The purpose of this study was to obtain general descriptive data about pain, its severity and treatment, as well as general attitudes toward cancer pain treatment in African American and Hispanic patients with breast cancer and with pain. One aim of this study was to determine if pain relief, treatment, and patient-related barriers to cancer pain might differ between these two ethnic groups. The data included the patients' subjective report of pain and its impact on function, the perception of the treating physician concerning the patients' pain, and the details of the pain treatment these patients are receiving. The survey instruments are based on ones used by Cleeland and the Pain Research Group at the University of Wisconsin (Cleeland et al., 1986) and in ECOG. Patient and physician questionnaires for this study have been tested within the ECOG system (Cleeland et al., 1994). The patient form is an adaptation of the Brief Pain Inventory (BPI). The physician questionnaire was adapted from a similar survey that was administered to nurses in a previous study.

Methods: African American and Hispanic women with previously diagnosed metastatic or recurrent breast cancer were approached by the research nurse during their regularly scheduled clinic visit. The women were asked to complete the BPI. This survey asks patients to rate their pain at its worst, least, and average for the last week, as well as their pain at the time of the study, on a 0 to 10 scale. Each scale is anchored by the words "no pain" at the 0 end and "pain as bad as you can imagine" at the other. Using the same type of scales, patients are also asked to rate how their pain interferes with several quality of life domains that include activity, walking, mood, sleep, work, and relations with others. These scales are anchored by "does not interfere" and "interferes completely". The patients were also asked to estimate the pain relief they were receiving from their pain treatment (in percent), and to answer questions about their perception of pain and attitudes toward taking analgesics. The BPI has been validated in culturally diverse groups and also in different language formats. The Spanish version, developed using a cross-translation method, has been validated in a multi-site study in Mexico and the Dominican Republic as part of a WHO demonstration project

(Cleeland, 1989a). The Spanish version has also been successfully used in multi-center studies in the U.S. (Cleeland et al, 1994). The pain and interference scales of the BPI are robust across different language and cultural groups (Cleeland et al., 1988; Serlin et al., 1995).

Physicians completed the "Physician Pain Assessment" survey form for each scheduled patient within 48 hours of the scheduled patient visit. This survey asked the physician to describe the patient's current pain treatment, to rate the patient's ECOG performance status, and to indicate the causes of the patient's pain. The physician had the patient's record when completing the survey but did not refer to the patient's completed BPI answers, and each physician signed a statement to that effect.

*Accrual:* Part of these data were collected in an ECOG survey of minority patients. These data included 40 Hispanic and 22 African American women with breast cancer and pain. This project collected an additional 17 Hispanic and 10 African American breast cancer patients, for a total sample size of 89 (57 Hispanic and 32 African American) breast cancer patients with cancer-related pain.

*Results:* The mean ages of the Hispanic (55.3) and African American (53.6) women with breast cancer were not significantly different. Seventy-five per cent of the Hispanic women and 70% of the African American women received an ECOG performance score in the range of 0-2, indicating the ability to function in basic daily activities. There was also no difference between the mean "worst pain" score for Hispanics (6.8 on a 0 to 10 scale) and African Americans (6.3). These data suggest that the groups were comparable in terms of demographics, disease status and pain severity.

Adequacy of treatment was estimated by using the Pain Management Index (Cleeland et al, 1994), a measure of whether or not patients were prescribed analgesics appropriate to the severity of their pain. The Index is based on the World Health Organization's recommendations for cancer pain management, as adopted by the AHCPR Guidelines for Cancer Pain Management (AHCPR, 1994). As has been found in other studies, the majority of these minority women were receiving analgesics of insufficient strength to manage their pain, although there was no heritage-based difference, with 64% of Hispanics and 55% of African Americans being under medicated with analgesics.

Because poor pain assessment has been identified as a factor in poor pain management (Cleeland et al., 1994), the degree of concordance between physician and patient about the severity of pain was indexed by the discrepancy between the patients' and physicians' ratings of the extent to which pain was interfering with the patients' activities. The patient-physician activity rating discrepancy score could range from -10 (complete disagreement: patient rating maximal interference, physician rating no interference) to +10 (physician rating maximal interference, patient rating none). The physicians in the present study underestimated the pain severity of 63% of the African American and 79% of the Hispanic women. Moreover, the physicians were significantly more likely to underestimate the pain severity of the Hispanic as compared to the African American women ( $p < 0.05$ ). The physicians also were asked to rate the adequacy of a patient's pain control on a 0-10 scale where 0 equals no pain and 10 indicates always has severe pain. The mean physician ratings for the Hispanic (3.5) and African American (3.9) women reflect the physicians' beliefs that their patients' pain is adequately managed. In contrast, the mean patient rating for their "average pain" was 4.8 for both Hispanic and African American women.

Several questions were asked about the patients' concerns about pain treatment, their need for additional information about pain management, and their view of the pain treatment that they were receiving. Table 1 demonstrates that several differences were found between the Hispanic and

needed more information about pain management (71% vs. 46%). A majority of both groups reported that they needed stronger pain medications (60% and 54%), although Hispanic women were more likely to say they needed more of their current analgesic prescription (48% vs. 22%). Even for those with appropriate prescriptions, a majority of Hispanics (57%) and African Americans (57%) took their analgesics two times a day or less, and African Americans were significantly more likely (77%) than Hispanics (47%) to take their analgesics only when necessary. There was no difference between the groups in the number of Hispanics (31%) and African Americans (17%) who worried that they might be taking too many medications. There was a tendency for Hispanics to be more worried (43%) about analgesic side effects than were African Americans (24%).

The results of this initial study documented that the majority of both Hispanic and African American women with breast cancer and pain were under medicated with prescription analgesics, and that their physicians underestimated the severity of the pain that their patients were experiencing. Hispanic women more frequently reported that they needed information about their pain and more of their current pain medication, and tended to be more concerned about the negative side effects of analgesics. While a majority of both groups were estimated to be incompletely compliant with presumed analgesic instructions (taking analgesics less often than would be typically recommended), African American women were significantly more likely than Hispanic women to report that they took their analgesics only when necessary.

#### **Study 002 - Health Professionals' Attitudes Toward Cancer Pain Management (Task 1)**

Surveys of health professionals have identified barriers and provided insight into current pain management practice patterns. Since it has been documented that minority cancer patients are at a greater risk for under management of pain, a survey of health professionals who treat this population should help in designing interventions that target minority cancer patients. We have gathered data on cancer pain management practice from a sample of physicians, nurses, and pharmacists who treat minority cancer patients of low socioeconomic status (SES).

The information from this study was used to (a) identify barriers to pain management which need to be addressed in educational interventions for patients in these minority study sites, (b) document the current status of pain treatment at the three study sites, and c) document the current pain management practice at the three study sites, providing information about health professionals' perception of the barriers to good pain management. The specific objectives of this study were (a) to determine the knowledge of cancer pain and its treatment among physicians, nurses, and pharmacists treating minority patients with cancer of low SES at three sites, (b) to determine the methods of pain control being utilized at these three sites, (c) to determine the staff's perception of barriers to pain management at these three sites, and (d) to compare the knowledge and attitudes of staff at these three sites with the results of cancer pain treatment as reported by patients in the "Outpatient Pain Needs Assessment Survey."

A shortened, booklet form of the Physician Cancer Pain Questionnaire developed by Charles S. Cleeland and the Pain Research Group at the University of Wisconsin was utilized (Cleeland et al., 1986). This questionnaire was the instrument used in a recent study of physicians in the Eastern Cooperative Oncology Group (VonRoenn et al., 1993). The questionnaire was designed to assess physicians' estimates of the magnitude of pain as a specific problem for cancer patients, physicians' attitudes about the adequacy of pain management for cancer pain, and their report of how they manage pain in their own practice setting. As a way of describing more specific pain management practice questions, they provided treatment recommendations for a patient presented in a scenario

format. Information was also gathered on the physicians' practice setting, training, and experience with caring for patients with cancer pain. The shortened version of the survey takes about 10 minutes to complete.

**Eligibility:** The eligible participants included all physicians, nurses, and pharmacists serving minority patients of low SES with cancer at the following sites: John Peter Smith Hospital, Fort Worth, TX; Jackson Memorial Hospital, Miami, FL; Los Angeles County Hospital, Los Angeles, CA; and LBJ General Hospital, Houston, TX. During the period August 1997 to August 1998, the study was completed at LBJ General Hospital. No participants were excluded on the basis of sex, age, race, or educational preparation. No inducements were offered for participation in this study. Receipt of the completed questionnaire was considered informed consent.

**Methods:** Eligible staff members were identified by the research nurse or data manager at each site. All nurses, pharmacists, and physicians with some patient care responsibilities for oncology outpatients were approached. The research nurse or data manager at each site hand-delivered a copy of the survey form, cover letter, and postage-paid addressed return envelope to each eligible staff member. Participants returned completed surveys to the Pain Research Group via a postage-paid envelope. The surveys did not include the name of the respondent, nor were the identification numbers in any way connected with respondents' names in order to insure confidentiality. After three weeks, site research staff redistributed the surveys to the staff member who had not responded. Study data were identified by staff category and by institutional site but not by name of participant to insure anonymity and confidentiality.

**Accrual:** The second survey distribution for this study was completed at three sites (Miami, Los Angeles, Fort Worth) in April 1996. The second distribution was completed at LBJ General Hospital in March 1998. We have received a total of 62 questionnaires from the four sites: 14 from Fort Worth, 21 from Miami, 14 from Los Angeles, and 13 from Houston. The response rates for Houston, Fort Worth, Miami, and Los Angeles were 41%, 78%, 60%, and 48%, respectively.

**Results:** The subject sample included 29 physicians, 28 nurses, and 5 pharmacists. The mean age of the respondents was 39.7 years (SD = 9.4). The subjects were 60% female, 12% Hispanic and 88% not of Hispanic origin. The racial distribution of the subjects was 63% white, 16% African American, 13% Asian or Pacific Islander, and 8% other.

A majority of the health professionals (56%) reported caring for over 100 cancer patients during the past 6 months. Eighty-seven percent of the health care professionals reported that the majority of the cancer patients they treat are members of an ethnic or racial minority group. A majority of the professionals (59%) also estimated that 50% or more of the cancer patients they treat have pain for more than one month. Moreover, 93% of the respondents indicated that the majority of all cancer patients suffer pain for longer than one month. Although over half of the health professional sample (63%) described pain control treatment in their own practice setting as good or very good, 30% rated it as fair and 7% described it as poor or very poor. When asked to describe the use of analgesic medication for cancer pain in their practice setting, 72% of the staff said that patients in their setting receive adequate pain treatment. Moreover, 63% of the health care professionals described themselves as more liberal than their peers concerning the use of analgesics for cancer pain.

**Evaluation of Pain Management Practices.** To assess the clinic staff's pain management practice, a hypothetical case scenario was presented: *A 40 year old male cancer patient is hospitalized with severe untreated back pain of more than 1 month duration, attributable to bone metastases without vertebral collapse. He weighs 70 kg., has no cardiovascular or respiratory problems, and has a disease prognosis of more than 24 months. He has no history of medication*

*allergies and is opiate naive. What would be your recommendation for initial pain management for this patient?*

Table 2 presents the staff's recommendations for the initial pain management regimen for the cancer patient described in the scenario. Most of the health professionals (98%) stated that they would prescribe an opioid analgesic, with 71% of the respondents recommending a "strong" opioid (morphine or a similar drug). However, 27% of the health professionals chose a "weak" opioid (codeine or an equivalent). Less than 2% of the staff chose an NSAID as the strongest analgesic to be used. Although 68% would administer the medication around the clock, 28% of the staff would administer the medication only as needed. The oral route of administration was recommended by 66% of the staff. Compared with the previous survey of ECOG physicians (Von Roenn et al., 1993), the health care professionals were more willing to prescribe a strong opioid (71% vs. 41%) for the patient in the scenario.

In the continuation of the scenario, the patient does not benefit from palliative radiotherapy to treat the pain. The professionals were asked to describe the most aggressive analgesic regimen that they would recommend. Given this scenario, 85% of the respondents included a potent opioid (morphine or equivalent) in their pain treatment recommendations. Only 8% of the professionals suggested a mild opioid as the most potent analgesic in the regimen. The oral or transdermal route of analgesic administration was chosen by 86% of the respondents. Fourteen per cent of the sample suggested intravenous administration.

The health care professionals were asked to rank a list of analgesic medications in terms of their preference for the treatment of prolonged moderate to severe cancer pain, based on their knowledge and experience. A large majority (94%) rated a strong opioid as their first choice. Of those who picked a potent opioid as their first choice, the following medications were chosen: morphine sulfate-SR (67%), morphine sulfate-IR (10%), fentanyl (7%), hydromorphone (7%), levorphanol (3%), Brompton cocktail (3%), and methadone (2%). In the previous survey of ECOG physicians, 62% of the respondents rated a strong opioid as their first choice of analgesic medications.

A large majority of the health care professionals (85%) stated that the most likely explanation for why a terminal cancer patient would request greatly increased doses of pain medication was that the patient was experiencing increased pain. The professionals treating the minority patients also were asked: At what disease stage (in terms of prognosis) would you recommend maximum-tolerated narcotic analgesic therapy for treatment of this patient's severe pain? Table 3 demonstrates that 46% of the health care professionals would prescribe maximum analgesia if the patient had less than 24 months to live, which was the longest prognosis of the possible responses. However, 46% of the professionals would wait until the patient had less than 6 months to live before recommending maximum analgesia. In the previous ECOG study, 31% of the respondents would wait until the patient had a prognosis of less than 6 months before prescribing maximum analgesia.

**Barriers to Pain Control.** The health professionals were asked to rank a list of potential barriers to optimal cancer pain management in terms of how they might impede cancer pain treatment in their setting. Table 4 portrays the percentage of respondents ranking each item as one of the top four barriers. Inadequate pain assessment, patient reluctance to report pain, and inadequate staff knowledge about pain management were reported as top barriers by over half of the health care professionals. Medical staff reluctance to prescribe opiates was prescribed as a top barrier by 39% of the professionals.

The responses of the health care professionals were compared with the results of the previous ECOG study of physicians from primarily non-minority clinics (Von Roenn et al., 1993). As with

the large physician sample, most of the health care professionals in the minority settings saw poor pain assessment, patient reluctance to report pain, and inadequate staff knowledge as major barriers. However, some differences in the rankings of the two professional samples were noted. Although the ECOG physicians from non-minority clinics did not rate lack of staff time as a significant barrier, 37% of the health professionals in the present sample felt that lack of staff time for pain treatment was a major barrier in their settings. Similarly, higher percentages of the health care professionals treating primarily minority patients ranked lack of access to a wide range of analgesics (19% vs. 3%), lack of available neuro-destructive procedures (14% vs. 5%), and lack of equipment or skills (13% vs. 6%) as important barriers.

**Education in Pain Management.** About half (51%) of the health professionals reported fair or poor training in cancer pain management. The remainder (49%) of the health professionals reported good or excellent training in cancer pain management. In the previous ECOG survey of physicians, only 12% of the sample reported medical school training in cancer pain management as excellent or good. In the present study, only 56% of the professionals identified constipation as the one side effect of opioid medications that does not decrease after repeated administration. Fourteen percent of the respondents were willing to admit that they did not know which side effect would not decrease.

#### **Study 004 - Perceived Pain Management Needs of Minority Outpatients (Task 1)**

We examined African American and Hispanic breast cancer patient attitudes toward pain management and current pain management practice through the use of structured patient interviews. Structured interviews allowed us to probe for previously unidentified barriers to pain management in these populations. In addition, tape-recorded interviews provided insight into the language style which was appropriate for the target audience of the educational videos.

The current study was the final part of Phase 1 (needs assessment) in the development of educational materials for low SES African American and Hispanic patients. The information from this study was used to identify barriers to pain management which were addressed in the educational interventions for patients. Results from the current study were used in conjunction with results from the Outpatient Pain Needs Assessment Survey and the study of Health Professionals' Attitudes Toward Cancer Pain Management, described above, to determine the issues which were addressed in patient education materials designed for African American and Hispanic breast cancer patients.

The primary objective of this study was to amplify our information about the perceived pain management needs of minority cancer patients of low SES. A second objective was to identify culturally specific language styles in order to ensure that educational materials appropriately reflected language used by the target populations in discussing cancer pain.

***Eligibility:*** Patients were recruited from the following participating sites: John Peter Smith Hospital, Fort Worth, TX; Jackson Memorial Hospital, Miami, FL; Los Angeles County Hospital, Los Angeles, CA. The subjects were outpatients seen in oncology clinics at the participating institutions. All of the patients had received a pathological diagnosis of cancer and had recurrent or metastatic disease. None of the patients had undergone surgery in the past 30 days. All of the patients reported chronic cancer-related pain and a pain worst score on the Brief Pain Inventory (BPI) short form of >4. In addition, the patients were  $\geq 18$  years of age and a member of the Hispanic or African American minority group. All of the patients had an ECOG Performance Status rating of 0, 1, 2, or 3.

Methods: A private room was made available in the oncology clinic at each site for the structured interviews. Oncology outpatients who met the eligibility requirements were asked to participate in the study. The research nurse or a designated interviewer conducted all interviews. Interviews were conducted in English or Spanish depending on patient preference. Interviews were tape recorded and transcribed later. In addition, the interviewer took notes summarizing the response to each question. These interview summaries were used in the case of audio or interpretation difficulties during the transcription of the interviews. On-Study Forms, BPI Short Forms, taped interviews and interview summaries were forwarded to the Pain Research Group for tape transcription, data entry, coding, and analysis.

The structured interview was developed by a committee that included members of the Pain Research Group, site investigators, and consultants with extensive clinical experience with patients in each of the target groups. The interview was translated into Spanish and then back-translated by two separate bilingual translators. The interviews took 30 to 60 minutes to complete.

Pain and pain interference were measured with the Brief Pain Inventory (BPI) Short Form. The BPI asks patients to rate their pain for the last 24 hours on 0-10 scales at its "worst", "least", "average", and "now". Each scale is bounded by the words "no pain" at the 0 end and "pain as bad as you can imagine" at the other. Using the same type of scales, patients are also asked to rate how their pain interferes with several quality of life domains including activity, walking, mood, sleep, work, and relations with others. These scales are bounded by "does not interfere" at the 0 end and "interferes completely" at the other. Issues of the validity and reliability of the BPI have been examined in detail (Daut et al., 1983; Cleeland, 1989b; Serlin et al., 1995). English and Spanish revisions of the BPI have recently been used in a group wide ECOG study of cancer pain and its treatment, following a study of its patient acceptability and its feasibility as a clinical trials tool (Cleeland et al., 1994; Hatfield et al., 1991).

Accrual: As of August 1998, 21 female patients with metastatic or recurrent cancer have been registered in the study. The Fort Worth site registered 1 patient; the Los Angeles site has registered 5 patients, and the Miami site has registered 15 subjects. Seventeen female patients (10 Hispanic, 7 African American) have completed the structured interview. Eleven of the patients have a diagnosis of metastatic breast cancer; the remaining 6 patients have other metastatic or recurrent cancers (lung, colon, lymphoma, myeloma). All of the patients had a pain worst score on the Brief Pain Inventory (BPI) short form greater than 4. The study is closed at the Miami site, which met its accrual goal. The study remains open at the Los Angeles site. However, it should be noted that ample data were collected from the three sites and analyzed to fulfill the objectives of the study and to facilitate completion of the educational materials. Our next goal with regard to this study is to publish the results in a peer-reviewed journal.

Results: The content analysis compared the responses of the African American and Hispanic women to questions in four general areas relevant to pain management: information and communication about pain, treatment of pain, meaning of pain, and demographic data that might impact pain treatment. The analysis indicated that the responses of the eleven patients with breast cancer are comparable to those of the six patients with other types of metastatic or recurrent cancer. The pain-related concerns of the two subgroups of women do not appear to differ significantly.

In the information and communication area, the Hispanic and African American patients reported receiving information about cancer and cancer pain from multiple sources. Fifteen of the seventeen women interviewed reported that their physician is a primary source of information about cancer and cancer pain. A majority of the women also reported their physician as the most trusted source of information about cancer pain for themselves and their families. Eleven of the women

reported using booklets as another important source of information. There were no differences between the African American and Hispanic women regarding their reliance on their physicians and written materials. Although several women commented that they would like to watch videos on cancer and cancer pain, they added that none were available to them. The Hispanic women were more likely than the African American women to use family members, friends, and/or other cancer patients as sources of information. Seven of ten Hispanic women mentioned these sources, as compared to three of the seven African American women.

When asked what kind of information received about cancer pain had been helpful, only 2 patients (one African American and one Hispanic) reported receiving helpful information about pain medications. Only one patient reported receiving helpful information about possible side effects of pain medication. A majority of the women in both ethnic groups stated that they have no difficulty talking about having cancer and cancer pain. Six of the seven African American women did report some difficulty talking about general physical problems.

All of the patients stated that they talk to their physicians about their pain. Only five patients indicated that they discuss their pain with a nurse. Several patients commented that a nurse is rarely present in their clinic setting. The majority of patients in both ethnic groups feel that their physician understands about their pain. The Hispanic patients also emphasized that their family talks to them about their pain.

In the treatment area, all of the patients reported receiving medications prescribed by their physicians. A majority of the patients in both ethnic groups were receiving opioid medications. Consistent with the results of Study 001, the majority of the patients interviewed were under medicated with prescription analgesics. There were no apparent differences between the African American and Hispanic women in this regard. The Hispanic patients were more likely than the African American patients to report many concerns about becoming addicted to pain medicine. The Hispanic patients also reported that their family members were very concerned about the pain medicine. A majority of the Hispanic but not the African American women were worried about the efficacy of pain medicine. A majority of the patients in both ethnic groups reported concerns about being strong and not leaning on pain medicines. The overall assessment of attitudinal barriers to effective pain management suggested that the Hispanic patients have higher barriers than the African American patients.

The patients in both ethnic groups did not report major difficulty in obtaining their prescribed pain medications from a pharmacy. Cost was not described as a major barrier. Prescriptions were typically filled and taken. Four of the ten Hispanic patients reported taking less of their pain medication than prescribed by their doctor. Only one patient in each ethnic group reported a problem with someone taking their pain medication from them. Gastrointestinal side effects from pain medications were commonly reported by both groups. Only one patient reported calling the cancer clinic about a side effect. Similarly, nearly all of the patients said that they would wait until their pain reached a 9 or 10 (on a 10-point scale) before calling the doctor, nurse, or clinic.

The African American and Hispanic patients described their pain in terms of sensations, associated emotions, and functional effects. The benefits of pain medications were described as feeling better, having a better mood, and being able to participate in work, family, and social activities. The demographic data indicate that the two ethnic groups are similar in terms of education, marital status, job status, and income. Most of the women are not married, have less than a high school education, and at least one child in the home. The average income is less than \$500 per month.

In sum, the results of the content analysis provided important information for the development of the educational materials. The analysis identified the perceived pain management needs of minority women of low SES who have metastatic cancer. The identification of these needs was used in the development of the educational materials for the clinical trial. For example, the patients in both ethnic groups appeared to be dependent on their physicians for providing trustworthy information about cancer pain management. Thus, the videotapes include physicians talking to their patients about cancer pain and available treatments. As Hispanic patients reported using family members and other cancer patients as important sources of information about cancer pain, these groups are included in the video and written materials.

The content analysis indicates a need for helpful information about pain medications, possible side effects (especially gastrointestinal effects), and how to deal with side effects. The patients also need education about contacting their physician or nurse before their pain level is severe. A majority of patients in both ethnic groups reported noncompliance or incomplete compliance with presumed analgesic instructions. This finding is consistent with the survey results from Study 001. The Hispanic patients and their families are very concerned about addiction to pain medication and demonstrate other attitudinal barriers to effective pain management. The Hispanic women are more concerned about the negative side effects of analgesics than the African American women. Similarly, the results of the structured interviews indicated that the Hispanic patients were more concerned about addiction and the efficacy of pain medicine than the African American patients. The patients in both groups can benefit from learning how to use pain rating scales to discuss their pain with health care providers. The use of a pain rating scale is described in both the videos and written materials.

### **Development of Training Materials (Task 2)**

Analyses of the first three studies (outpatient pain needs assessment survey, health professionals attitudes toward cancer pain management and perceived pain management needs of minority outpatients) and the results of the focus groups with minority breast cancer patients guided the development of the video and written materials. As noted above, the videos for African American and Hispanic breast cancer patients include physicians, as well as nurses, who are experts on pain management. Both videos emphasize the importance of communicating with one's physician about pain. In addition, the videos provide an example of how to communicate with a physician in a clinic setting. The videos and booklets also teach the use of a simple pain rating scale. Thus, the videos include appropriate skills training to accomplish the goal of improved pain management. The women in both ethnic groups are encouraged to take their medications as prescribed and to contact their physicians for increased pain and/or difficulty with medication side effects. Both videos include an example of how to contact the physician (see Appendix I).

The results of the focus groups of minority breast cancer patients and the initial studies, as well as consultation with experts on minority patient education, guided the development of the written materials. A booklet on pain management designed specifically for African American women with breast cancer was developed. The booklet for Hispanic women with breast cancer was developed and is undergoing a final revision based on suggestions from our consultants. Both booklets will be printed by the end of September 1998. The booklets address the topics recommended by the focus groups and supplement the information provided in the videos. The

reading level of the booklets has been analyzed as the fifth grade level. This level is consistent with the average educational background of our target populations at the three sites.

The consultants to our project recommended that the control group receive an educational video and booklet on a topic unrelated to pain management. These materials will control for the effects of attention and providing credible educational information. Dr. Karen Syrjala, Director of Biobehavioral Services at the Fred Hutchinson Cancer Center, suggested using materials on nutrition similar to ones she employed in a previous study of pain management interventions (Syrjala et al., 1995). The video "Feeling Better with Food - Good Nutrition for People with Cancer Undergoing Treatment" will be shown to the control group. A Spanish version of the video, "Sintiendose Mejor Con Alimentos", was completed by University of Texas Television. The control group also will be provided with a booklet on nutrition for cancer patients, "Feeling Good - Nutritional Planning to Improve Your Cancer Therapy". This booklet is published by Mead Johnson and will be provided for our study. A Spanish translation of the booklet was completed by our research staff and was published by Mead Johnson.

In sum, the production of our educational materials will be completed by the end of September 1998. We anticipate closing the pilot phase of the clinical trial in October 1998 and initiating the full clinical trial (**Task 3**). The extension of the grant period will allow us to complete the clinical trial, analyze the data, and prepare the final report.

### **Pilot Study of Pain Management Skills for Outpatient with Breast Cancer (Task 3)**

The purpose of the pilot study is to train the site research nurses and data managers in the procedures for the clinical trial (e.g., patient identification, subject recruitment, data management, data transfer). Each of the three sites is piloting the study and will attempt to accrue five to fifteen minority cancer patients. The video and handbook are those currently used in an Eastern Cooperative Oncology Group clinical trial (ECOG 3Z93) that also examines patient education for pain control. These materials, designed for majority patients, are not expected to be as effective as the tailored materials produced by this project.

*Methods:* The patient eligibility criteria for the pilot study are similar to those for the clinical trial: (1) patient with recurrent or metastatic breast cancer, (2) outpatient, (3) African American or Hispanic, (4) 18 years of age or older, (5) pain worst score of 4 or greater, (6) ECOG performance status of 0, 1, or 2, (7) no current major psychiatric illness, (8) no major surgery within the past 30 days, (9) no current palliative radiotherapy to the site of pain, (10) no change in chemotherapeutic regimen with the past 14 days, and (11) lower socioeconomic status. In addition, patients in the pilot study must be English-speaking as the ECOG educational materials are only available in English.

Patients who agree to participate in the study and provide written informed consent are shown the videotaped presentation on pain management and receive a handbook on cancer pain treatments. The research nurse/data manager meets with the patient to discuss any questions and to stress the importance of reporting pain and lack of pain relief to the health care team. The patients' physicians continue to treat the patients' pain at their discretion. Patient assessments are scheduled at baseline (day one) and during weeks 2, 5, and 7. The outcome measures include the Brief Pain Inventory, SF-36 Health Survey, Outcome Expectancy and Self-Efficacy Questionnaire (OESE), and the Physician Pain Assessment Survey.

Accrual: The pilot study was initiated in February 1998 after grant funds became available to all sites. Five women with metastatic or recurrent breast cancer have been registered in the study: one patient at LBJ Hospital and four patients at Jackson Memorial Hospital in Miami. Recruitment has been difficult due several factors. First, the educational materials were designed for English-speaking majority patients. This problem will be resolved in the clinical trial with the use of culturally appropriate materials in Spanish and English. Second, the schedule of follow-up assessments is difficult for many patients to follow given their treatment schedules. The time periods for follow-up assessments in the clinical trial have been modified in order to fit the patients' scheduled clinic visits.

An additional issue that arose during the pilot study was the appropriateness of some of the outcome measures for our patient population. The patients reported that the SF-36 Health Survey and OESE were too long and difficult to complete. Based on this feedback, we modified the clinical trial protocol and changed the SF-36 to the SF-12 Health Survey and the OESE to a simple 10-item Pain Control Scale. The English and Spanish versions of the new outcome measures have been reviewed by oncology patients at LBJ Hospital and judged to be reasonable ones to complete.

In sum, our experiences with the pilot study have confirmed the necessity of producing ethnic and culturally appropriate educational materials on pain management. As a result of the pilot, the clinical trial protocol has been modified to facilitate patient accrual and retention in the study. Our target date for initiating the clinical trial is October 1998.

## CONCLUSIONS

This project documents that the majority of Hispanic and African American women are not receiving analgesics of an appropriate strength for their pain, and that physicians underestimated pain severity in these minority breast cancer patients by as much as 77%. Improving patient-health care professional communication about pain should be associated with more appropriate analgesic prescription. Underestimation of pain severity can be due to any of the following: inadequate assessment of pain and pain relief, inadequate staff knowledge of pain management, patient reluctance to report pain and lack of staff time, all of which were reported by the health professionals as major barriers to pain management in our three project sites. Critical goals of the educational materials are to encourage patients to report pain and to give them the skills to report pain and the adequacy of their pain relief. Our educational and video materials address the reluctance of minority breast cancer patients to report pain and encourage them to do so before pain becomes very severe. In addition, the training materials provide information about how to take analgesics and side effect management. Both patient-based studies indicate that both groups of women report that they need more of this information, but few receive it.

Several of the concerns that our Hispanic and African American consultants thought would be important to include in the video and educational materials were not borne out by the assessment phase. For example, the results of the content analysis do not indicate major difficulties in obtaining prescribed analgesic medications. Also, although the investigators and consultants had speculated that financial, transportation, or other social problems might interfere with obtaining medications, few patients reported these types of barriers. Similarly, availability of the medications in the pharmacy was rarely mentioned. The patients also did not report problems with having analgesic medications stolen or taken away for reasons other than theft. Thus, the patient educational materials do not address these areas.

The studies also indicate that Hispanic and African American breast cancer patients have different educational needs. In addition to the obvious requirement for both English and Spanish versions of the materials, the specific content receives differential emphasis. Hispanics may be more concerned with becoming addicted to medication and worrying about using "too much." They also had more concerns about whether analgesics really relieve pain. The Hispanic materials include a greater emphasis on the family as involved in the pain treatment, with ways of reassuring family about the minimal risk of addiction to opioids used for pain control. African American breast cancer patients may tend to be more isolated in negotiating their pain treatment. Their educational materials include special reinforcement for being their own advocates for pain relief. African Americans are also more likely to take their medications only when needed rather than as prescribed, and the pharmacologic rationale for around-the-clock analgesics receives special emphasis in their educational material.

The results of the three studies indicate that breast cancer patients feel a need for and can benefit from accurate information about analgesic medications and how to adhere to a regular medication schedule. Patients in both ethnic groups are concerned about possible side effects and will receive education about how to identify and cope with them. Data from all four studies demonstrate the need for culturally appropriate patient education regarding patient-health care provider communication. Patients will be encouraged to discuss their pain with their doctors and nurses, to use pain rating scales, and to report major changes in pain level or difficulty with side effects. Patients who learn how to assertively request pain relief should receive effective pain management from their health care providers.

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**Table 1. Comparison of Hispanic and African American Breast Cancer Patients on Attitudes Related to Pain Treatment**

Item *	Hispanic women	African American women	p values
Need more information	71%	43%	< 0.01
Need more of current analgesic medication	48%	20%	< 0.02
Need stronger analgesic medication	60%	50%	NS
Concerned about using too much med.	31%	15%	NS
Problems with side effects from med.	43%	19%	<0.04
Taking analgesic med. ≤ 2 times/day	57%	57%	NS
Taking analgesic med. on prn basis	47%	75%	< 0.02

\*Percentage of women responding "yes" to the item

**Table 2. Response to the Scenario:** A 40-year-old male cancer patient is hospitalized with severe untreated back pain of more than 1 month duration, attributable to bone metastases without vertebral collapse. He weighs 70 kg., has no cardiovascular or respiratory problems, and has a disease prognosis of more than 24 months. He has no history of medication allergies and is opiate naive. What would be your recommendation for the initial pain management regimen for this patient?

Analgesic Regimen	Percent of Respondents
Strong Opioid	70.9
Mild Opioid	27.3
NSAID	1.8
Around the Clock	67.9
P.O.	66.1

**Table 3. Response to the Question:** At What Disease Stage (Prognosis) Would You Recommend Maximum Tolerated Analgesia for Treatment of the Cancer Patient's Severe Pain?

Prognosis	Frequency	Percent
Less than 24 months	24	46
Less than 12 months	4	8
Less than 6 months	8	15
Less than 3 months	8	15
Less than 1 month	6	12
Less than 1 week	2	4

**Table 4.** Barriers to Optimal Cancer Pain Management Reported by Health Care Professionals at Four Study Sites

Barrier	Percentage *
Inadequate pain assessment	68.5
Patient reluctance to report pain	53.6
Inadequate staff knowledge about pain management	51.0
Medical staff reluctance to prescribe opiates	38.5
Lack of staff time to attend to patients' pain	36.5
Patient reluctance to take opiates	35.7
Nursing staff reluctance to administer opiates	20.4
Lack of access to a wide range of analgesics	18.8
Lack of access to professionals who practice specialized methods	18.0
Excessive state regulation of prescribing analgesics	17.8
Too much paper work	15.9
Patient inability to pay for analgesics	14.6
Lack of psychological support services	14.0
Lack of available neuro destructive procedures	13.6
Lack of equipment or skills	12.8

\* Percentage of respondents who selected the item as one of the top four barriers in the survey.